MEDICAL DEVICE SAFETY ALERTS

Alaris Medical Systems IVAC Model 591 Volumetric Infusion Pump

DIR 12106

Incident: The TGA has received an incident report from a hospital, involving the Alaris Medical Systems IVAC Model 591 Volumetric Infusion Pump, and the over infusion of a patient. It appears that the knob inside the door of the pump housing, enclosing the administration set, had broken. This knob activates the pump, so the pump was not able to control the infusion, and this resulted in free-flow with over infusion of the patient. The breakage seems to have occurred between scheduled maintenance checks. Nursing staff at the hospital is trained to check for this problem, but in this case the fault was not detected. The hospital involved is in the process of shifting these pumps out of critical care areas, in favour of more modern pumps with enhanced safety features.

Recommendation: Users should consider the appropriateness of these pumps for critical care infusions, and the need for vigilant training, maintenance, and procedural checks and warnings when using these pumps.

Disetronic H-Tron and H-Tron plus Insulin Pumps

Incident: There have been cases where Disetronic insulin pumps have delivered more insulin than what was programmed when the patients have worn the pump while swimming or bathing. This is contrary to instructions for use of this type of device.

Recommendation: Wearing this type of pump in the bath or whilst swimming is not recommended. The sponsor of Disetronic Insulin Infusion Pumps has issued a safety alert to all users of the pumps reminding them that they must not wear the devices when bathing or swimming.

Flexima Drainage Catheter

Incident: The TGA was notified of a problem report involving a Flexima catheter being used to inject alcohol into a renal cyst. The tip of the catheter separated from the rest of the catheter because alcohol used in a procedure, called sclerosing, remained in the catheter and caused damage to it. Sclerosing is a form of treatment that involves injecting the cyst with alcohol to destroy cells within the capsule to prevent regrowth. While this method is well established, the use of this type of catheter to introduce the alcohol is not recommended. The intended use of this catheter is as a drainage catheter only.

Recommendation: It is important that medical devices are used only for their intended purpose and in accordance to the instructions for use found in the product information. Only catheters that are designated as catheters for injection should be used to inject substances such as alcohol, after ensuring that the catheter is compatible with the fluid to be infused. The product information or the manufacturer should be able to help in cases where there is some doubt.

The instructions for use of the Flexima catheter have been amended to include statements regarding its incompatibility with alcohol.

Incompatibility of Intravenous Delivery Systems

DIR 12458

Incident: A patient arriving in the operating theatre already had intravenous access via a cannula, capped with a Clave needle-less bung. The anaesthetist connected a Go Medical triple lumen V-set to this Clave bung and commenced the infusion. A Metoraminol infusion was connected to one of the outlets and the Propofol to the other while an infusion line was connected to the main large lumen line of the V-set. The infusion pump used to infuse Propofol, alarmed occlusion and was switched to "piggy-back" into the main infusion line because a cause could not be identified. The patient was then anaesthetised but became hypotensive. Not long after this the Metoraminol infusion pump also displayed an occlusion alarm.

Both the Clave bung and the Go Medical triple lumen V-Set were sent to the TGA for analysis. The V-set has three outlets, which open at the end of the luer connector, although two of these openings are moulded into the edge of the luer slip connector. The Clave bung has a silicone sleeve in the clave, which seals the connector when not in use. When the V-set is introduced into the clave bung, the silicone sleeve in the Clave bung occludes the two outlets on the edge of the luer slip connector of the V-set.

Recommendations: Both of these devices are widely used. Since the Clave is a needle-less connector, the use of this combination of devices is likely to increase.

When using this combination of devices, the Clave bung should be placed upstream of the V-set. The sponsor of the V-set, Go Medical issued a safety alert to this affect to all of their customers.

Peaston IEC Medical Appliance Coupler, Cat P18. Manufacture 1994.

DIR 12529

Incident: A nurse received an electric shock when plugging the mains cable into the back of the medical device after it was noticed that the "no charge light" on the medical device diagnostics was on. The cable was sent to the TGA and inspection showed damage to the cable at the point where it enters the moulded appliance coupler, which included some evidence of arcing by way of blackening. There was also mechanical damage at other locations along the cable. The cable appeared to have been tightly wound over time, as the cord sheath was wavy and twisted.

The fatigue in the cable caused damage to the insulation of the cable, and exposed and fractured a section of the wiring, which explains the 'no charge light' on the medical device diagnostics. When the cord was pushed or wriggled into the device, the active wire was exposed causing arcing and blackness at the break point and the electric shock.

Recommendations: Australian Standard AS 2500 - *A guide to the safe use of electricity in patient care* - provides guidance on scheduled inspection and maintenance of medical electrical equipment, including mains cables for that equipment. AS/NZS 3551 - *Technical management programs for medical devices* - provides guidance on inspection and testing to be carried out by biomedical engineering staff, or contractors, under such a program.

Mains cables, because of their relatively low cost, are generally disposed of rather than repaired. Prior to disposing of faulty or worn cables they should be permanently disabled to prevent any further use.

Mains cables should be unplugged and stored neatly when not in use. They should never be tightly wrapped, twisted or unplugged by pulling on the cable.

Supply and Use of Unregistered or Unlisted Devices

Incident: A medical device** sent to the TGA from one of the State Coroners was not listed, registered or entered onto the Individual Patient Use (IPU) scheme. This device was an active implantable device that has been implanted in only a few patients in Australia, although several thousand patients overseas have had this device implanted.

The State Coroner assisted the TGA by providing the details of the device, manufacturer and report sent to them by the attending doctor. The TGA contacted the manufacturer who supplied information about the implanting surgeon and some device history, including a safety alert issued by the manufacturer.

The TGA was advised that the surgeon was unaware of the proper procedures for informing the TGA of the use of an unapproved medical device. The surgeon was informed of the Individual Patient Use (IPU) Scheme that allows medical practitioners access to unapproved medical devices where there is a special patient need.

In this case, the implanting surgeon had received the safety notice prior to the implantation of this device, but unfortunately the device still failed.

Recommendation: All medical device users should ensure that the device they wish to use is either listed or registered on the Australian Register of Therapeutic Goods (ARTG). The Individual Patient Use Scheme can be used to allow access to unapproved medical devices, subject to TGA approval, where there is a special patient need. For further information about the IPU Scheme or to obtain the application form, please contact the Clinical Section of the Conformity Assessment Branch on (02) 6232 8679.

** The device name has been withheld to protect the identity of the surgeon

Use of Incompatible Syringes in Syringe Drivers

Incident: The TGA received notification of several incidents associated with the use of syringes that were incompatible with the syringe drivers (syringe pump) they were being used with. The manufacturers of the syringe drivers stipulate in their instructions for use that only certain brands of syringes can be used in these drivers. The reason they have stated this in their instructions is that they have tested the driver with these syringes and found that they deliver the dose accurately. If other types or brands of syringes are used, there may be errors in the volume of drug delivered. The best dose accuracy can only be assured if the syringe specified in the syringe driver's product information is used.

This has been the case in the incidents reported. For example, B Braun 50/60ml syringes should not be used with the 'P' series IVAC syringe infusion pumps. Furthermore BD syringes should not be used with some Terumo syringe drivers, such as the STC 523. Incorrect delivery volumes may result in life threatening situations, depending on the drug being delivered.

Recommendation: It is important that users are aware of the instructions for use for syringe drivers under their care and that only the syringes that the syringe driver manufacturer recommends are being used. The stock of syringes used in syringe drivers should be segregated from the stock of general purpose syringes, unless they are of the same brand and type.

This is a safety issue, which could cause a permanent injury or death to the patient if the instructions for use are not followed.

Vaporisers: Risk of Simultaneous Use

DIR 12449

Incident: An incident occurred where two vaporisers were able to operate simultaneously causing the patient to be overdosed with anaesthetic agents. There is a potential for a serious life threatening incident to occur if users are not aware of a problem that can exist if anaesthetic vaporisers are not operated using a safety interlock back-bar. The Medical Devices Agency (MDA) in the United Kingdom has also recognised that there is a problem with vaporisers that are not fitted with safety interlock pins on the back bars of anaesthetic machines. The MDA have also received a report of an incident involving the simultaneous use of two vaporisers causing a sudden drop in a patient's blood pressure. If the interlock pins have never been fitted or have been removed, this will allow the use of more than one vaporiser at the same time.

Recommendation: The TGA recommends that users should only have one vaporiser on the anaesthetic machine back bar at any one time. It is also recommended to check whether the pins preventing the fitting of the TEC3 type vaporisers have been removed. If so contact your anaesthetic machine representative for advice and a possible conversion kit.

MEDICAL DEVICE INCIDENT REPORTING AND INVESTIGATION SCHEME STATISTICS REPORT
Device Incident Reports 01/01/2001 to 31/03/2001

Number received: 139

Cause of Problem	
Biocompatibility	9
Component failure	30
Contamination	5
Design	16
Diagnostic Inaccuracy	3
Electrical	18
Labelling	1
Maintenance	3
Manufacture	18
Material/Formulation Deficiency	14
Mechanical	9
Not Device Related	10
Other	15
Packaging/Sterility	2
Quality Assurance	10
Unknown	28
Wear/Deterioration	8

Effect	
Death	8
No Injury	92
Serious Injury	8
Temporary Injury	31
Result of Investigation	
Bulletin Article	3
Compliance Testing	3
No Further Action	44
Not Investigated	49
Other	5
Problem Not Confirmed	9
Product Improvement	14
Recall/Hazard Alert	12
Refer to GMP	4
Safety Alert	11
User Education	7

Source Category	
Medical Administrator	4
Specialist	15
Coroner	1
TGA	4
Nurse	17
Blood Bank	18
Hospital Supply Service	16
Other	5
Patient/User	2
Sponsor	46
Overseas Advice	6
Biomed Engineer	5

TGA THERAPEUTIC GOODS ADMINISTRATION

Incident Report Investigation Scheme
PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8695 Facsimile: (02) 6232 8555

Commonwealth Department of Health and Aged Care

Correction: "Use of Incompatible Syringes in Syringe Drivers" TGA News Issue 35, June 2001, Insert.

Subsequent to the publication of the TGA News Safety Alert on the use of incompatible syringes in syringe drivers, the TGA wishes to clarify a statement made in the above article.

In the example given it was stated that "BD syringes should not be used with some Terumo syringe drivers such as the STC 523". However, there are several types of syringes manufactured by Becton Dickinson (BD). Whilst no one BD syringe is compatible with all syringe drivers, BD manufactures syringes that are compatible with every syringe driver currently on the Australian market. BD Plastipak® syringes are not compatible with Terumo STC 523 syringe driver, however BD Precise® syringes are compatible with that driver.

Amended Recommendation: Users should check with both the syringe and syringe driver manufacturer to ensure that the syringes being used are compatible with the syringe driver. The stock of syringes used in syringe drivers should be segregated from the stock of general-purpose syringes, unless they are of the same brand and type.

For further information, users should contact the syringe supplier or the TGA Medical Device Incident Report Investigation Scheme on 1800 809 361.

Thursday, 5 July 2001